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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,344	01/04/2002	Daniel M. Cimbora	2318-288-II	2255

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MYRIAD GENETICS INC.
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EXAMINER	
LANDSMAN, ROBERT S	
ART UNIT	**PAPER NUMBER**
1647	

MAIL DATE	DELIVERY MODE
07/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/035,344	CIMBORA, DANIEL ET AL.	
	Examiner	Art Unit	
	Robert Landsman, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,46 and 48-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,46 and 48-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

A. The Response to the Board Decision filed 7/11/07 has been entered into the record.

B. Claims 1, 46 and 48-50 are pending and are the subject of this Office Action.

2. Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

A. Claims 1, 46 and 48-50 remain rejected under 35 USC 101. Applicants argue the claimed proteins and/or associated biochemical pathways are targets for drug development, the protein complexes can be used to screen for modulators of that protein, the protein complex and/or the interacting partner. Applicants further argue that the "PTO has not provided adequate evidence to establish a *prima facie* case to doubt the assertion in the specification that the protein complex between AKT1 or AKT2 and FNTA, TRPD, KIAA0728, PPL, Golgin-84, CLIC 1, and AKR7A2 are useful for screening for modulators of AKT 1 or AKT2, which are associated with physiological pathways and disorders, one particular pathway asserted being apoptosis" and further argue that, "to the contrary, the PTO merely alleges 'no evidence is provided in the specification to associate the claimed complexes with any specific physiological pathway or function.'"

These arguments have been considered, but are not deemed persuasive. First, the use of this complex to screen for modulators of the complex is credible and specific. However, it is not substantial. The specification does not characterize the protein complex. Applicants have, respectfully, only provided a description of the individual proteins in that complex. Therefore binding sites, signal transduction mechanisms, etc. are not identified ***as they pertain to the complex***. Significant further experimentation would be required of the skilled artisan to characterize the complex and search for ligands. Since this asserted utility is not presented in mature form so it could be readily used in a real world sense, the asserted utility is not substantial. To quote the Board Decision, "simply put, to satisfy the 'substantial'

utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public."

Applicants further argue that they have disclosed what they assert is a physiologically relevant set of protein-protein interactions as evidenced in the literature by the fact that some of the claimed proteins complexes are associated with the same or similar biochemical pathways in the literature, the yeast two-hybrid system used to identify the protein interactions is very robust and well controlled to eliminate false positives, the network of proteins provide additional confirmatory evidence of the association of these complexes with specific pathways. These proteins and their associated biochemical pathways were disclosed in the specification as being therapeutic targets. Applicants support this assertion by citing paragraph [0019] of the instant specification – that AKT1 and AKT2 are involved in cell proliferation and apoptosis and that the AKT pathway is a major target for drug development for cancer and other diseases.

Again, this argument has been considered, but is not deemed persuasive. The Examiner is not questioning the role of the individual AKT1 and AKT2 proteins. As stated by the Board Decision, "the specification provides no evidence that the ***complex*** of it with AKT1 or AKT2 is associated with the disease pathway. In sum, the specification provides no information about the specific physiological pathway or disorder which ***is associated with the protein complex***."

Applicants argue that Kun Jiang teach the association of FNTA and AKT2 and state that "since both FNTA and AKT2 are both known to play important roles in the physiological pathway of apoptosis, one of ordinary skill in the art would reasonably conclude that the presently discovered protein-protein complex claimed between FNTA and AKT2 would indeed provide a presently available utility for an effective method of screening for modulators of the complex to affect the apoptotic pathway."

This argument is also not deemed persuasive. Though FNTA inhibitors and AKT2 are associated apparently in function, there is no demonstration in the art that FNTA, itself, complexes with AKT2. Applicants have only argued that "farnesyl transferase ***inhibitors*** play an active role in modulating apoptosis, strongly implicating a role for the claimed FNTA (farnesyl transferase) protein's involvement in the apoptotic pathway as well." A similar argument can be made over Mitsuuchi, as relied upon by Applicants.

Finally, and similarly, Applicants argue that these proteins are involved in "a broad array of disorders." Again, however, it is the individual proteins, themselves, which are implemented in these disorders, including cell proliferation and apoptosis, ***not the complexes***. To this effect, the Board stated "we find the assertion in the specification that the complex is useful because it is 'involved in mammalian physiological pathways' insufficient to meet the utility requirement because it is neither substantial nor specific. "

3. Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 1, 46 and 48-50 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 2- 4 of the Office Action dated 4/20/05 as well as for the reasons given in the above rejection under 35 USC 101. Applicants argue that the claimed invention is enabled because it has utility as argued previously. Applicants' arguments have been fully considered, but are not found to be persuasive for the reasons discussed above.

4. Conclusion

A. No claim is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 10 AM – 7 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol at 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman, Ph.D.
Primary Examiner
Art Unit 1647